REMARKS

Status of the Claims

Claims 33-43 remain pending in the present application, Claims 1-32 having been canceled herein in response to a restriction requirement, subject to applicants' right to file a divisional patent application directed to such claims. Claims 33, 34 and 35 have been amended to more clearly define the recited subject matter.

Amendment to the Abstract

The Examiner has objected to the abstract of the disclosure because the title of the invention should be deleted from the page. The appropriate correction has been made.

Claims Rejected Under 35 U.S.C. § 102(e)

Claims 33-41, and 43 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,387,077 (Klibanov et al. - hereinafter referred to as "Klibanov"). Applicants respectfully disagree for the following reasons.

In the interest of reducing the complexity of the issues for the Examiner to consider in this response, the following discussion focuses on independent Claims 33-36.

The patentability of each remaining dependent claim is not necessarily separately addressed in detail. However, applicants' decision not to discuss the differences between the cited art and each dependent claim should not be considered as an admission that applicants concur with the Examiners conclusion that these dependent claims are not patentable over the disclosure in the cited references. Similarly, applicants' decision not to discuss differences between the prior art and every claim element, or every comment made by the Examiner, should not be considered as an admission that applicants concur with the Examiners interpretation and assertions regarding those claims. Indeed, applicants believe that all of the dependent claims patentably distinguish over the references cited. In any event, a specific traverse of the rejection of each dependent claim is not required, since dependent claims are patentable for at least the same reasons as the independent claims from which the dependent claims ultimately depend.

Patentability of Independent Claim 36 over Klibanov

The cited art does not teach or suggest *rotating a container about its own axis* AND then *dispensing fluid when the container is not rotating.*

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In Claim 36, step (b) recites the step of *rotating the container about its axis before dispensing the fluid*, and step (d) recites the step of *dispensing the fluid when the container is not rotating*.

Klibanov discloses several embodiments. However, each embodiment disclosed by Klibanov ***is incapable*** of dispensing the fluid when the container is not rotating. The Examiner has asserted that Klibanov discloses rotating the container about its axis before dispensing the fluid in the container, citing to column 3, lines 53-55. The Examiner further asserts that Klibanov specifically discloses ***dispensing the fluid when the container is not rotating***, citing to column 3, lines 43-55. Respectfully, the Examiner is incorrect that Klibanov discloses dispensing in the absence of rotation.

The portion of Klibanov to which the Examiner refers is reproduced below:

> *An embodiment of the method comprises rotating the container about an axis of rotation sufficient to suspend the agent and delivering the agent from the container by exerting a force upon the actuator sufficient to operate the actuator as the container is rotating to maintain the agent in suspension. The rotating and the delivering may occur simultaneously or the rotating may occur before the delivering. Alternatively, the delivering may be interrupted while maintaining the rotating. In certain embodiments, the container may be rotated in a planetary orbit about the axis of rotation.* In other embodiments, the container axis and the axis of rotation are collinear. The container may be prefilled with the agent, such as a contrast agent. (Emphasis added, Klibanov, col. 3, lines 42-55.)

Note that the above portion simply does not teach or suggest ***dispensing the fluid when the container is not rotating.***

There are two embodiments disclosed by Klibanov, a first embodiment which corresponds to the above portion that has been italicized, and a second embodiment which corresponds to the above portion that has been underlined. It must be understood that Klibanov absolutely does not disclose any embodiment that dispenses fluid without simultaneous rotation.

Klibanov's first embodiment is shown in FIGURE 1, and is described at column 4, line 39 to column 7, line 13. This first embodiment rotates the container in a planetary orbit about a longitudinal axis of threaded spindle 54 (see column 6, line 44). Thus, this embodiment cannot read on applicants' Claim 36, as Claim 36 ***requires*** that the container is rotated about its own axis. Furthermore, a single motor is responsible for both rotation and plunger displacement (i.e., fluid dispensing). A clutch enables the plunger to be selectively controlled, such that depending on the position of the clutch the plunger either moves or is stationary when the motor is energized. However, no clutch is provided to control the rotation of the container, thus whenever the motor is

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energized the container is rotating in a planetary orbit. Claim 36 ***requires*** that fluid be dispensed when the container is not rotating, and the clutch/motor configuration of Klibanov's first embodiment makes that impossible (i.e., the plunger cannot be moved without rotating the container in a planetary orbit).

Klibanov's second embodiment is shown in FIGURES 2-4, and is described at column 7, line 14 to column 9, line 2. The second or alternative embodiment of Klibanov rotates the container about its own axis (see column 8, line 42), and fluid delivery and rotation occur simultaneously (see column 8, lines 5-8 and lines 55-56). In this second embodiment, rotation and dispensing must occur at the same time because in Klibanov's second embodiment a single motor is used to move the plunger and rotate the container, and no clutch is provided to decouple those motions. The operation of the motor is described in column 8, lines 39-48, as both rotating the tumbler about the housing axis and advancing the tumbler such that the proximal portion of tumbler 108 is engaged to plunger 130 so as to advance it. In other words, the motor responsible for the plunger movement (i.e., responsible for fluid delivery) is also responsible for rotation, and thus Klibanov's second embodiment simply cannot dispense fluid without simultaneous rotation. When the motor stops, there is no rotation and no fluid dispensing. Thus, Klibanov's second embodiment cannot read on applicants' Claim 36, as Claim 36 ***requires*** that dispensing occur in the absence of rotation.

Accordingly, the rejection of independent Claim 36 under 35 U.S.C. § 102(e) as being anticipated by Klibanov should be withdrawn. Dependent claims are inherently patentable for at least the same reasons as the claims from which they depend; thus the rejection of dependent Claims 37-41, and 43 should also be withdrawn.

In the event that the Examiner should consider the modifications to Klibanov to achieve an equivalent invention (i.e., a method of dispensing fluid wherein a container is first rotated about its own axis for a period of time, followed by dispensing of fluid in the absence of rotation), applicants respectfully submit that the modifications required are not trivial. Significantly, in each of the two embodiments disclosed by Klibanov, the same prime mover both moves a plunger for fluid dispensing and enables the fluid container to be rotated. The first embodiment employs a clutch such that the plunger need not move when the prime mover is energized. However, the container will rotate in a planetary orbit whenever the prime mover is energized. In Klibanov's second embodiment, when the prime mover is energized both fluid dispensing and rotation occur.

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Significantly, in each of the embodiments disclosed by Klibanov, the plunger cannot move (i.e., there can be no fluid delivery) unless the container is being rotated. In other words, Klibanov's principle of operation is to enable fluid delivery only while the container is being rotated (although rotation can occur without fluid delivery).

Applicants' principle of operation requires decoupling of fluid delivery with rotation. In other words, applicants' principle of operation is to dispense fluid after rotation has been terminated. MPEP 2143.01 specifically provides that "if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." Modification of Klibanov to achieve an equivalent to that which applicants have claimed would impermissibly require changing Klibanov's principle of operation. MPEP 2143.01 expressly forbids such a modification.

Patentability of Independent Claims 33, 34, and 35 over Klibanov

Claims 33, 34 and 35 each specifically recite the step of dispensing a fluid *independently* of the rotation of a container. These claims have been amended to specifically recite that *rotation of the container is not required in order for dispensing of the fluid to occur* (Claim 35 uses slightly different wording to convey the same meaning).

Klibanov does not teach or suggest an equivalent step. As discussed above, both of Klibanov's embodiments enable fluid delivery only while the container is being rotated (although rotation can occur without fluid delivery in Klibanov's first embodiment). Thus, Klibanov clearly teaches a method of dispensing that is *dependent* upon rotation of the container (i.e., no rotation, no fluid delivery). Accordingly, the rejection of independent Claims 33, 34 and 35 under 35 U.S.C. § 102(e) should be withdrawn.

As discussed in detail above, applicants' principle of operation is to dispense fluid after rotation has been terminated. MPEP 2143.01 specifically provides that "if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." Modification of Klibanov to achieve an equivalent to that which applicants have claimed would impermissibly require changing Klibanov's principle of operation. MPEP 2143.01 expressly forbids such a modification. Thus, not only does Klibanov not anticipate the claimed invention,

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Klibanov cannot serve as the basis for an obviousness type rejection that requires modification of Klibanov's principle of operation.

Claims Rejected Under 35 U.S.C. § 103(a)

Claim 42 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Klibanov in view of U.S. Patent No. 5,355,373 (Salmon et al. - hereinafter referred to as "Salmon").

Claim42 recites that the frequency modulation and phase characteristics of a motor are matched to a rotation rate of the syringe to reduce pulsatility. The Examiner notes that Salmon discloses an electric motor whose frequency modulation and phase characteristics appear to be readily adjustable. Applicants respectfully submit that simply because Salmon discloses that those characteristics ***can be*** adjusted is not equivalent to teaching or suggesting that adjusting those characteristics to match a container's rotation *can reduce pulsatility.* As the Examiner has noted, Salmon's stepper motor is an improvement over prior art stepper motors because Salmon's control over frequency modulation and phase characteristics enables infinite steps to be achieved. Salmon simply does not teach that controlling frequency modulation and phase characteristics of a motor to match the rotation rate of a container will reduce pulsatility.

Furthermore, as noted above, Klibanov cannot serve as the basis for an obviousness type rejection that requires modification of Klibanov's principle of operation. Claim 42 requires that fluid delivery occur without rotation, and Klibanov cannot be modified to achieve such operation per MPEP 2143.01. Thus, the combination of Klibanov and Salmon cannot achieve an equivalent to that which is recited in applicants' Claim 42.

Conclusion

In consideration of the amendments to the claims and the Remarks set forth above, it is applicants' position that all claims in the current application are patentable over the art of record. The Examiner is thus requested to pass this case to issue without further delay. In the event that any other issues remain, the Examiner is invited to telephone applicants' attorney at the number listed below.

Respectfully submitted,

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